

The Examiner states that it is not clear how the epitope is hidden and recognized as foreign by the immune system. Applicants respectfully traverse on the ground that cryptic epitopes are well-known in the field of immunology and one skilled in the art would understand how a cryptic epitope remains unrecognized by the immune system. As disclosed in the specification, a cryptic epitope is either hidden or modified, thereby preventing destruction of the corresponding determinant. *See* page 3, lines 21-37. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

The Office Action indicates that the metes and bounds of "at risk of an HIV infection" is not clear. While Applicants do not acquiesce to this rejection, Applicants have amended claim 28 and 29 to advance prosecution. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

Claim 28 Is Enabled

Claim 28 stands rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the specification does not reasonably provide enablement for diagnosing a patient having HIV infection using an antibody to detect a cryptic epitope. Applicants respectfully traverse this rejection.

In order to make a rejection for alleged enablement, the Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. MPEP § 2164. The Examiner, whenever a rejection on this basis is made, must explain *why* he doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of his own with acceptable evidence or reasoning which is inconsistent with the contested statement. Absent this explanation and evidence, the rejection is improper and should be withdrawn.

Such is the case here, the Examiner posits that the specification fails to disclose the use of the claimed antibody as a diagnostic to detect a cryptic epitope. Applicants direct the Examiner to page 11, lines 25-39, wherein the specification discloses a method for detection and diagnosis. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

Claim 28 is further rejected on the grounds that beta-2-microglobulin is found in the urine of patients with certain immune system disorders. Applicants submit that the instant

invention is not directed to the detection of beta-2-microglobulin in patient urine samples. In contrast, the present invention discloses a method for detecting beta-2-microglobulin in patient serum samples. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

Claim Rejection - 35 U.S.C. § 101

Claims 26 and 27 are rejected under 35 U.S.C. § 101 because they read on a product of nature. In their present form, amended claims 26 and 27 avoid this rejection.

Claim Rejection - 35 U.S.C. § 102

Claims 26, 27, 29 and 30 stands rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Liabeuf. Applicants respectively traverse.

It is well settled that in order for a reference to anticipate, the reference must describe every element of the claimed invention. MPEP §2131. Liabeuf does not describe an epitope comprising 15 amino acids or less and an amino acid sequence, Pro-Lys-Ile. Therefore, Liabeuf does not anticipate the instant invention. Accordingly, Applicants respectfully request withdrawal of the rejection.

CONCLUSION

Applicants request an indication that reference A1 on PTO-1449 was considered by the Examiner.

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. § 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date 5/14/13

FOLEY & LARDNER

Customer Number: 22428



22428

PATENT TRADEMARK OFFICE

Telephone: (202) 672-5569

Facsimile: (202) 672-5399

By Sean A. Passino (45943)
Stephen B. Maebius SEAN A. PASSINO FOR
Attorney for Applicants
Registration No. 35,264

Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge deposit account No. 19-0741 for any such fees; and applicant hereby petitions for any needed extension of time.

Version With Markings To Show Changes Made

In the specification:

On Page 1, between lines 3 and 4:

--This application is a continuation of U.S. Application No. 09/599, 549, filed June 23, 2000 (now abandoned), which is a divisional of U.S. Application Serial No. 08/973,551, filed February 19, 1998, (now U.S. Patent No. 6,113,902), which application is a the
nNational sStage of International Application No. PCT/FR96/01006, filed June 28, 1996,
published in a non-English language ~~which is a continuation of 09/599,549 filed June 23, 2000.~~--

In the claims:

26. (Amended) An isolated antibody which binds to at least one isolated B2-microglobulin cryptic epitope, said epitope has 15 amino acids or less and comprises an amino acid sequence, Pro-Lys-Ile.
28. (Amended) A method for diagnosing a patient having HIV [or at risk of an HIV infection], comprising detecting the presence of said cryptic epitope in said patient with an antibody according to claim 26.